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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

Submitter:	BIOMET *3i* 4555 Riverside Drive Palm Beach Gardens, FL 33410
Establishment Reg. Number:	1038806
Contact:	Martha I Garay Senior Regulatory Affairs Specialist BIOMET *3i* 4555 Riverside Drive Palm Beach Gardens, FL 33410 Tel. 561-776-6923 Fax. 561-514 6316 Email martha.garay@BIOMET.com
Date Prepared:	November 18th, 2011
Trade/Proprietary Name:	OSSEOTITE® 2 Dental Implants
Common/Usual Name:	Root-Form Endosseous Dental Implant
Classification Name/ FDA Reviewing Branch:	Endosseous Dental Implant / Dental Panel
Device Classification/Code:	Class II - 21 CFR §872.3640 / DZE
Predicate Device Manufacturer:	K100724 - OSSEOTITE II MODEL XIFOSSXXX / BIOMET 3i K063286 – OSSEOTITE Dental Implants / BIOMET 3i
Purpose of the *SPECIAL* 510(k) notice:	The reason for this *Special* 510k submission is to request clearance for a modification to a device that has been cleared under the 510(k) process referred to herein as ***OSSEOTITE® 2 Dental Implants***. Root-Form Endosseous Dental Implants are referenced under 21 CFR §872.3640 and are considered Class II devices.
Device Description:	***OSSEOTITE® 2 Dental Implants*** are similar to predicate BIOMET *3i* OSSEOTITE Implants, currently being sold worldwide. ***OSSEOTITE 2® Dental Implants*** are provided with the proprietary OSSEOTITE dual acid-etched surface which has been in commercial distribution since market clearance in 1995 and are made of Commercially Pure Titanium.

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Implants have a straight wall design, with an External Hex Connection. ***OSSEOTITE®2 Dental Implants*** are offered in diameters of 3.25, 3.75, 4.0, 5.0, and 6.0 in varying lengths from 3 mm to 15 mm. Size appropriate cover screws are provided with each implant.

Indications for Use:

BIOMET 3i Dental Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or with a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.

OSSEOTITE®2 Dental Implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.

Technological Characteristics :

The predicates and ***OSSEOTITE® 2 Dental Implants*** have a number of very similar and equivalent design / technological characteristics, as follows:

Criteria	Predicate OSSEOTITE II MODEL XIFOSSXXX (Internal Hex) K100724	Predicate OSSEOTITE; OSSEOTITE NT; XP; TG Implant(s) (External Hex) K063286	Proposed OSSEOTITE®2 Dental Implant(s) (External Hex) K111216
Implant Lengths	Ø3.25: 8.5, 10.0, 11.5, 13.0, 15.0, 18.0mm Ø4.0: 8.5, 10.0, 11.5, 13.0, 15.0, 18.0, 20.0mm Ø5.0: 8.5, 10.0, 11.5, 13.0, 15.0mm Ø6.0: 8.5, 10.0, 11.5, 13.0, 15.0mm	Ø3.25: 7 (actual:6.6mm), 8.5, 10, 11.5, 13, 15mm Ø3.75: 7 (actual:6.6mm),, 8.5, 10, 11.5, 13, 15mm Ø4: 7 (actual:6.6mm),, 8.5, 10, 11.5, 13, 15mm Ø5: 7 (actual:6.6mm),, 8.5, 10, 11.5, 13, 15mm Ø6: 7 (actual:6.6mm),, 8.5, 10, 11.5, 13, 15mm	Ø3.25: 6.5, 8.5, 10, 11.5, 13, 15mm Ø3.75: 6.5, 8.5, 10, 11.5, 13, 15mm Ø4: 6.5, 8.5, 10, 11.5, 13, 15mm Ø5: 6.5, 8.5, 10, 11.5, 13, 15mm Ø6: 6.5, 8.5, 10, 11.5, 13, 15mm
Implant Body Diameters	Ø3.25, 4.0, 5.0, 6.0mm	Ø3.25, 3.75, 4, 5, 6mm	Ø3.25, 3.75, 4, 5, 6mm
Seating Platform Diameter	Ø3.25: 3.4mm Ø4: 4.1mm Ø5: 5.0mm Ø6: 6.0mm	Ø3.25: 3.4mm Ø3.75: 4.1mm Ø4: 4.1mm Ø5: 5.0mm Ø6: 6.0mm	Ø3.25: 3.4mm Ø3.75: 4.1mm Ø4: 4.1mm Ø5: 5.0mm Ø6: 6.0mm
Material	Commercially Pure Titanium	Commercially Pure Titanium	Commercially Pure Titanium

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Biocompatible	Yes	Yes	Yes
Thread Design	• 60° thread & 0.6mm pitch (Straight-Wall) • 35° thread & 0.8mm pitch (Straight-Wall)	• 60° thread & 0.6mm pitch (Straight-Wall) • 60° thread & 0.9mm pitch (Straight-Wall)	• 60° thread & 0.6mm pitch (Straight-Wall) • 35° thread & 0.8mm pitch (Straight-Wall)
Implant Design	Straight-walled implant body	Straight-walled implant body	Straight-walled implant body
Self Tapping Feature	Integrated cutting flutes with apical taper	Integrated cutting flutes with apical taper	Integrated cutting flutes with apical taper
Implant Surface	Full OSSEOTITE®	Full OSSEOTITE®	Full OSSEOTITE®
Color-Coding	• Anodized Seating Surface • Color-Coded Labeling	• Anodized Seating Surface • Color-Coded Labeling	• Anodized Seating Surface • Color-Coded Labeling
Packaging	Packaged in sterile tray with cover screw	Packaged in sterile tray with cover screw	Packaged in sterile tray with cover screw
Sterilization	Sterile (Gamma Irradiation)	Sterile (Gamma Irradiation)	Sterile (Gamma Irradiation)
Shelf Life	5 Years	5 Years	5 Years
Implant Placement Protocol	Per BIOMET *3i* Surgical Catalog CATSM	Per BIOMET *3i* Surgical Catalog CATSM	Per BIOMET *3i* Surgical Catalog **CATM2**
Implant/Abutment Mating Connection	Internal Hexagon Connection	External Hexagon Connection	External Hexagon Connection
Mating Components	All BIOMET *3i* Certain® Restorative Components	All BIOMET 3i External Hex Restorative Components	All BIOMET *3i* External Hex Restorative Components

Performance Data:

BIOMET *3i* has conducted Design Verification Testing according to ISO 14801:2007 *"Dentistry – Dynamic Fatigue Test for Endosseous Dental Implants"* on the ***OSSEOTITE® 2 Dental Implants*** under this submission. All testing conducted met the acceptance criteria and evaluated the worst case scenario including 30° pre-angled abutments as compared to predicate BIOMET *3i* designs commercially in the marketplace. Performance testing data indicates that changes to the predicate device are safe and effective for its intended use and it demonstrate to be substantially equivalent. Bench Testing conducted demonstrates that the proposed device meets the mechanical properties recommendations by FDA and ISO Standards.

Clinical Data:

Two clinical reports on ***OSSEOTITE® 2 Dental Implants*** are included with this submission:

- *"Insertional Torque Force, Osseotite 2 Placement Data, Pressure Necrosis"* dated September 21st, 2011. This report provides background information on the thread design for the ***OSSEOTITE® 2 Dental Implants*** and a summary of two clinical projects where insertion torque forces are measured. The report includes an analysis of the actual insertion torque forces

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for this implant design, the success of the implants at a defined follow-up time point post loading, and a review of the implant failures and their baseline torque values. Additionally, the subject of pressure necrosis that has been alluded with implant placement procedures associated with high insertion torque forces is discussed.

- *"BIOMET 3i Insertion Torque Report"*, dated November 10, 2011. This report provides an overview of the implant placement experience data for the ***OSSEOTITE® 2 Dental Implants***, including a tabulation of individual insertion torque values and implant failures.

Performance Standards:

The following FDA Guidance Document for this type of product was utilized in this submission: ***"Guidance for Industry and FDA Staff: - Special Controls Class II - Root Form Endosseous Dental Abutment/ Implant".*** Also, Testing was conducted following ISO standard **14801:2007** Dentistry -- Implants – ***"Dynamic fatigue test for endosseous dental implants".*** The test articles met all predetermined acceptance criteria.

Substantial Equivalence:

The ***OSSEOTITE® 2 Dental Implants*** included in this submission have the same intended use, indications for use, technological characteristics, and principles of operation as previously cleared BIOMET ***3i*** OSSEOTITE Certain® Internal and External Connection Implants per the 510(k) numbers referenced in the Predicate Devices section above.

Refer to the following substantial equivalence data table:

Predicate OSSEOTITE II MODEL XIFOSSXXX (Internal Hex) K100724	Predicate OSSEOTITE; OSSEOTITE NT; XP; TG Implant(s) (External Hex) K063286	Proposed OSSEOTITE® 2 Dental Implant(s) (External Hex) K111216
Intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment.	Intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment.	Intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment.
Intended for single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.	Intended for single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.	Intended for single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework, and to

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		retain overdentures.
Provide immediate function when good primary stability is achieved with appropriate occlusal loading to restore chewing function.	Provide immediate function when good primary stability is achieved with appropriate occlusal loading to restore chewing function.	Provide immediate function when good primary stability is achieved with appropriate occlusal loading to restore chewing function.

Conclusion:

OSSEOTITE® 2 Dental Implants and predicate designs have the same intended use, indications for use, similar technological characteristics, and principles of operation. The major technological difference between the ***OSSEOTITE® 2 Dental Implants*** and its predicates is:

- The ONLY change is the modification of the abutment connection from an internal feature to an external hex engagement.

The differences noted above do not present new issues of safety or effectiveness for the ***OSSEOTITE® 2 Dental Implants***.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Martha I. Garay
Senior Regulatory Affairs Specialist
BIOMET 3i, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

NOV 18 2011

Re: K111216
Trade/Device Name: OSSEOTTE® 2 – Dental Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: November 10, 2011
Received: November 14, 2011

Dear Ms. Garay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111216

Device Name: **OSSEOTITE® 2 –Dental Implants**

Indications for Use:

BIOMET *3i* Dental Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or with a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.

OSSEOTITE® 2 Dental Implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.

Prescription Use ___X___ **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) **AND/OR** **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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